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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/319,521 06/04/99 PITTENGER

M 640100-326

EXAMINER

HM12/1009

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DECLoux, A

ART UNIT

PAPER NUMBER

1644

10

DATE MAILED:

10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/319,521

Applicant(s)
Pittenger et al.

Examiner
DeCloux, Amy

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jul 17, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-3, 5-13, 36, 39, and 42-59 is/are pending in the application.

4a) Of the above, claim(s) 1-3, 5-13, 36, and 39 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 42-59 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: _____

DETAILED ACTION

Note: The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

1. Applicant's amendment, mailed 7-13-2001 (Paper No. 9), is acknowledged.
2. The rejections of record can be found in the previous Office Action, mailed 1-17-01 (Paper No. 7). In view of applicant's amendment mailed 7-13-2001, the outstanding rejections have been withdrawn. However, in view of applicant's cancellation of all elected claims and replacement with new claims, new grounds of rejection are being applied.
3. The disclosure is objected to because of the following informalities: page 21, 7th line from the bottom, contains a provisional application number, which is impermissible. Appropriate correction is required.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
5. Claims 42-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnstone et al (US Patent #5,908,784), as evidenced by www.voigtglobal.com/Cellgro_basal_liquid.htm.

The '784 patent teaches a composition and process for the invitro chondrogenesis of human mesenchymal precursor cells and the in vitro formation of human chondrocytes therefrom, wherein said composition comprises isolated human mesenchymal stem cells in a three dimensional format and at least one chondroinductive agent is in contact therewith. The mesenchymal stem cells are preferably isolated , culture expanded human mesenchymal stem cells in a chemically defined serum free environment and are condensed in close proximity, such as in the form of a three dimensional cell mass, e.g. packed cells or a centrifugal pellet. The chondroinductive agent is preferably selected, individually or in combination from the

group consisting of I) a glucocorticoid such as dexamethasone; ii) a member of the transforming growth factor beta super family such as BMP-2 or BMP-4, TGF-beta1; iii) a component of the collagenous extracellular matrix such as collagen I; and IV) a vitamin A analog such as retinoic acid. Particularly preferred is the combination of dexamethasone and TGF-Beta-1. (See entire patent, especially column 2, lines 5-33)

The '784 patent further teaches that the serum free media comprises a chemically defined minimal essential medium, ascorbate or an analog thereof, an iron source, insulin or an insulin like growth factor, in an Eagle's based media such as DMEM (column 6, lines 42-45, column 4, lines 26-34, column 2, lines 43-53).

www.voigtglobal.com/Cellgro_basal_liquid.htm teaches that DMEM contains from 1 to 4.5 gr/L glucose. Therefore, the referenced teachings anticipate the claimed invention.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.

Serial No. 09/319,521
Art Unit 1644

-4-

Patent Examiner,
Group 1640, Technology Center 1600
October 9, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~162~~/644